IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

MARCTEC, LLC,

Plaintiff/Counterclaim Defendant,

v.

JOHNSON & JOHNSON and
CORDIS CORPORATION,

Defendants/Counterclaim Plaintiffs. **Case No. 07-cv-825-DRH**

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER ON DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

HERNDON, Chief Judge:

This matter came before the Court on the Motion, pursuant to Rule 56 of the Federal Rules of Civil Procedure, by Cordis Corporation and Johnson & Johnson (collectively "Cordis") for Summary Judgment of Noninfringement of U.S. Patent Nos. 7,128,753 ("the '753 patent") and 7,217,290 ("the '290 patent") (collectively "the patents-in-suit" or "Bonutti patents"). D.I. 68. After consideration of that motion and subsequent briefing (D.I. 108, D.I. 125), the Court makes the following findings of fact, based on the Court's claim construction and facts over

which there is no dispute or can be no dispute as a matter of law, as well as, conclusions of law.

FINDINGS OF FACT

1. On July 18, 2008, Cordis moved for summary judgment of noninfringement. D.I. 68.

2. On March 31, 2009, this Court issued an opinion and order construing disputed claim language from the '753 and '290 patents consistent with the specification and the prosecution history. D.I. 175. Cordis's motion for summary judgment of noninfringment concerns limitations that were construed in that opinion.

3. In order to demonstrate that the Cypher stent infringes the patents-in-suit under the Court's claim construction, MarcTec would need to show, *inter alia*, that: (1) Cypher is a surgical device or implant, (2) only a portion of the Cypher stent is expandable, (3) the polymers in Cypher's drug-eluting coating do not adhere to the stent at room temperature, (4) the polymers in Cypher's drug-eluting coating are bonded to the device by the application of heat, and (5) "that heat must be sufficient to cause the material to be bonded to become flowable, tacky and adherent." D.I. 175 at 28; *see also id.* at 23, 26, 29.

I. The Asserted Patents

A. The Claims of the '290 Patent

4. In this action, plaintiff MarcTec L.L.C. ("MarcTec") alleges that the Cypher stent, sold by defendant Cordis, infringes claims 1-6, 8, 10 and 14 of the '290 patent. Claim 1 is an independent claim. Claims 2-6, 8, 10 and 14 depend from claim 1 and thus incorporate all of its limitations.

5. Claim 1, with the five limitations which are the basis for Cordis's Motion for Summary Judgment of Noninfringement in bold italics and numbered, reads as follows:

> [1] ***An implant for implantation in a human body*** comprising: a tubular member having a channel and mechanically expandable upon activation of a delivery mechanism from a contracted condition in which the tubular member has a first cross sectional size in a plane perpendicular to a longitudinal central axis of the tubular member to an expanded condition in which [2] ***at least a portion of the tubular member has a second cross sectional size*** in a plane perpendicular to the longitudinal central axis of the tubular member, the second cross sectional size being ***larger than the first cross sectional size*** to thereby lock the tubular member against tissue in the human body; and [3] ***a first component bonded to at least a portion of the tubular member*** and formed of a heat bondable material that includes a therapeutic agent selected from the group consisting of a tissue ingrowth promoter and an antibiotic, wherein the heat bondable material is [4] ***non-flowable and non-adherent at room temperature*** and [5] ***becomes flowable, tacky, and adherent upon the application of heat***.

B. The Claims of the '753 Patent

6. MarcTec also alleges that the Cypher stent infringes claims 1, 3 and 4 of the '753 patent. Claims 3 and 4 depend from independent claim 1 and thus

incorporate all of its limitations.

7. Claim 1, with the five limitations which are the basis for Cordis's motion for summary judgment in bold italics and numbered, reads as follows:

> [1] ***A surgical device for implantation in a body*** comprising: an [2] ***implant, at least a portion of which is expandable***; and [3] ***a polymeric material bonded to the implant***, wherein the polymeric material is a thermoplastic, includes a therapeutic agent, is [4] ***non-flowable and non-adherent at room temperature***, and [5] ***becomes flowable, tacky, and adherent upon the application of heat***.

II. Prosecution History

8. Dr. Peter Bonutti is a named inventor on both of the patents-in-suit.

9. As the Court previously found, during prosecution of the patents-in-suit, the Patent Office ("PTO") rejected Dr. Bonutti's proposed claims as invalid over U.S. Patent No. 5,102,417 ("the '417 patent"), which issued to Dr. Julio Palmaz. D.I. 175 at 9; D.I. 70, Ex. L at 3. Dr. Palmaz is the inventor of the balloon-expandable coronary stent. D.I. 175 at 9; D.I. 125, Ex. 2 (Denardo Tr.) 30:14-19. In his early patents, including the '417 patent – written before balloon-expandable stents existed – Dr. Palmaz used the terms "expandable intraluminal vascular graft" and "expandable prosthesis" to refer to stents. D.I. 175 at 9; D.I. 70, Ex. G (Palmaz '417 patent) at 5:26-35, 6:44-54.

10. In the '417 patent, Dr. Palmaz makes a point of distinguishing intraluminal procedures utilizing stents from conventional surgery. D.I. 175 at 9; D.I. 70, Ex. G at 1:26-35.

11. The Palmaz '417 patent is prior art to the patents-in-suit and teaches a polymer/drug coating "placed upon the wall surfaces" of the stent. D.I. 70, Ex. G at 11:3-8, 11:26-34; D.I. 175 at 9.

12. As this Court has found (D.I. 175 at 9-10), when the PTO rejected Dr. Bonutti's claims as invalid over the Palmaz stent (D.I. 70, Ex. L at 3), Dr. Bonutti represented to the PTO – and thus the public – that his invention did not include intraluminal grafts (*i.e.*, stents), and, further, that his invention is directed to devices for use in surgical applications, in contrast to Palmaz's balloon-expandable stent, which is not a surgical device:

> Palmaz discloses an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway (col. 6., lns. 21-23). . . . Applicants, on the other hand, disclose, inter alia, an assembly for use in surgical applications in humans.

D.I. 70, Ex. M at 5.

13. In addition, Dr. Bonutti represented to the PTO that his invention is different from the device disclosed by Dr. Palmaz because his invention, unlike the device described by Dr. Palmaz, has a material bonded to it by the application of heat. D.I. 175 at 10; D.I. 70, Ex. M at 6. Thus, Dr. Bonutti represented to the PTO that "[i]n contrast [to the device disclosed by Dr. Palmaz], Applicants' implant includes a heat bondable material which is bonded to an implant by the application of heat." D.I. 70, Ex. M at 6 (emphasis added); D.I. 175 at 10. In his '417 patent, Dr. Palmaz does not disclose the use of heat to bond the coating to the stent. D.I. 175 at 10. Dr. Bonutti relied on this difference to differentiate his invention from the

prior art Palmaz patent, and, thus, to obtain allowance of his claims. Id.; D.I. 70, Ex. M at 6. As this Court has held, in doing so, "Dr. Bonutti disclaimed devices in which a material is bonded to the device other than by the application of heat." D.I. 175 at 10; see id. at 23.

14. Dr. Bonutti also amended the claims of the patents-in-suit to require that the material bonded to the implant or tubular member "is non-flowable and non-adherent at room temperature and becomes flowable, tacky, and adherent upon the application of heat." D.I. 175 at 10-11; D.I. 70, Ex. M at 2; D.I. 70, Ex. O at 2.

15. The amendment was made in direct response to the Examiner's rejection of the claims as anticipated by the disclosure of a coating with drug "placed upon wall surfaces of tubular shaped members" in the prior art Palmaz patent. D.I. 70, Ex. M at 5-6; D.I. 70, Ex. G at 11:3-8, 11:26-34; D.I. 175 at 11.

16. Dr. Bonutti told the PTO that the purpose of his amendment was to "highlight" the distinction between his invention and the prior art Palmaz patent:

> Palmaz teaches an implant including an absorbable polymer coating placed upon wall surfaces of tubular shaped members. In contrast, Applicant's implant includes a heat bondable material which is bonded to an implant by the application of heat.
>
> To highlight this distinction, Applicants have amended independent claims 11 and 27 to include, inter alia, a polymer material which is non-flowable and non-adherent at room temperature and becomes flowable, tacky, and adherent upon the application of heat.

D.I. 70, Ex. M at 6.

17. As this Court has explained, "this amendment made clear that Dr.

Bonutti's invention required the application of heat to a heat bondable material to cause that material to transform from one state (non-flowable and non-adherent) to a different state (flowable, tacky and adherent)." D.I. 175 at 11.

III. Claim Construction

18. In moving for summary judgment of noinfringement, Cordis asserts that undisputed evidence establishes that its Cypher stent does not have several claim limitations of the Bonutti patents, as construed by this Court in its March 31, 2009 claim construction opinion and order (D.I. 175).

A. Mechanical Claim Limitations

19. As construed by this Court, the claims of the patents-in-suit exclude stents. D.I. 175 at 19. Specifically, the Court has construed the terms "a surgical device" from claim 1 of the '753 patent and "an implant" from claim 1 of the '290 patent to mean "a device for use in surgical applications, but not including an expandable intraluminal vascular graft or expandable prosthesis for a body passageway." Id.

20. The Court also construed the language of the claims as covering devices that expand in part, not completely. Id. at 20. Specifically, the Court construed the language "an implant, at least a portion of which is expandable" from claim 1 of the '753 patent to mean that "a portion, but not all of the implant, is expandable." Id. at 20. In addition, the Court construed the language "a tubular member . . . mechanically expandable . . . from a contracted condition . . . to an expanded condition in which at least a portion of the tubular member has a second cross

sectional size . . . larger than the first cross sectional size to thereby lock the tubular member against tissue in the human body" from claim 1 of the '290 patent to mean that "a portion, but not all, of the tubular member is expandable so that when expanded, its cross-sectional size is larger than its initial cross-sectional size. The expansion of only a portion of the tubular member enables it to be locked against tissue." Id.

B. Claim Limitations Requiring Heat

21. As construed by this Court, the claims of the patents-in-suit require heat to cause the polymeric material to bond to the implant. Id. at 26-29.

22. The Court construed the phrase "a polymeric material bonded to the implant" from claim 1 of the '753 patent to mean "a polymeric material is bonded to the implant by the application of heat." Id. at 26. The Court construed the phrase "a first component bonded to at least a portion of the tubular member" from claim 1 of the '290 patent to mean "a material is bonded to the tubular member by the application of heat." Id.

23. The Court construed the phrase "the polymeric material . . . is non-flowable and non-adherent at room temperature" from claim 1 of the '753 patent to mean that "the polymeric material cannot flow at room temperature and cannot adhere to the implant if placed on the implant at room temperature." Id. at 27. In addition, the Court construed the phrase "the heat bondable material is non-flowable and non-adherent at room temperature" from claim 1 of the '290 patent to mean that "the heat bondable material cannot flow at room temperature and cannot adhere to

the tubular member if placed on the tubular member at room temperature." Id. at 27-28.

24. The Court construed the phrase "the polymeric material . . . becomes flowable, tacky and adherent upon the application of heat" from claim 1 of the '753 patent to mean that "the polymeric material is bonded to the implant by the application of heat sufficient to cause the polymeric material to become flowable, tacky and adherent." Id. at 28-29. In addition, the Court construed the phrase "the heat bondable material . . . becomes flowable, tacky and adherent upon the application of heat" from claim 1 of the '290 patent to mean that "the heat bondable material is bonded to the tubular member by the application of heat sufficient to cause the heat bondable material to become flowable, tacky and adherent." Id. at 29.

IV. Cordis's Cypher Stent

A. The Cypher Stent And Its Mechanical Properties

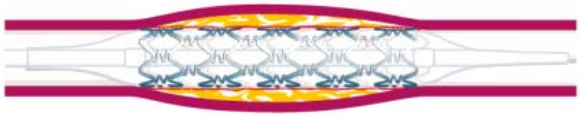
25. In this action, MarcTec alleges that Cordis's Cypher stent infringes the asserted claims of the '290 and '753 patents. The Cypher stent is a balloon-expandable drug-eluting stent. It is a small, slotted metal tube with a coating of polymers and drug adhered on its outer and inner surfaces. D.I. 70, Ex. X; D.I. 70, Ex. W at CMT16148.

26. The Cypher stent is introduced into a blood vessel by percutaneous (through the skin) insertion and delivered via a balloon catheter to the desired location in a coronary artery. The placement of the stent (or stenting) is a "non-

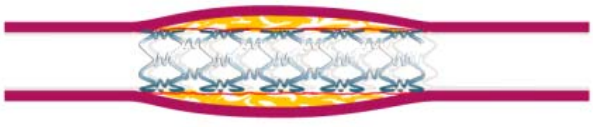
surgical" procedure. D.I. 70. Ex. S at CMT510697. As this Court has found, a stent is a "non-surgical" device. D.I. 175 at 4.

27. The stent is premounted on a balloon catheter in a contracted form and introduced in the body in this form. D.I. 70, Ex. Y at CMT1437997.

Once the Cypher stent is positioned at a site of the blockage, the balloon is inflated and the stent fully expanded along its entire length. Id.



After the Cypher stent is expanded by the balloon, it stays fully expanded. The balloon is then deflated and removed with the stent remaining in place. The expanded Cypher stent acts as a scaffold to keep the artery open and allow blood flow. Id.



B. The Cypher Drug-Eluting Coating

28. Cypher's polymer/drug coating (or drug-eluting coating) has three components: two polymers and a drug. D.I. 70, Ex. W at CMT16148; D.I. 68, Ex. 1 Declaration of Cynthia A. Maryanoff, Ph.D. ("Maryanoff Decl.") ¶6. The polymers are poly-n-butyl methacrylate ("PBMA") and poly(ethylene-co-vinyl acetate) ("PEVA"). The drug is sirolimus. D.I. 70, Ex. W at CMT16148; D.I. 68, Ex. 1 (Maryanoff Decl.) ¶6.

29. The technology used to place this polymer/drug coating on the wall surfaces of a stent is known as solution casting. D.I. 68, Ex. 1 (Maryanoff Decl.) ¶7. Solution casting is a method of applying a material to a surface by first dissolving the material in a solvent, applying the mixture to a surface and allowing the solvent to evaporate, thus leaving the material behind, adhered to the surface. Id. at ¶8. Solution casting has been known for centuries. It is how paint is applied to a surface, by mixing pigment in a solvent, applying the mixture to the surface and allowing the solvent to evaporate. Paint dries as the solvent evaporates. Once the solvent evaporates, the pigment is adhered to the surface. Id. The Cypher stent is coated in exactly the same way. Id.

30. Before the polymer/drug coating is applied, the stent surface is first prepared with a silane reagent followed by the deposition of a Parylene C primer coat. Id. at ¶9. The polymers, PBMA and PEVA, and drug, sirolimus, are dissolved in a solvent. This solution is then sprayed on the surface of the primed stent. The polymer/drug coat is left on the surface once the solvent evaporates and adheres to that surface. Id. The placing of polymers and drug on the Cypher stent occurs

entirely at room temperature. No heating is involved in placing the polymers and drugs on the stent. Id. at ¶10.

i. Applying the Base Coat and Top Coat Solutions

31. The polymer/drug coat is applied by first spraying what is called a base coat solution onto a Parylene C-coated stent. The base coat solution is a 1:1:1 mixture of PBMA, PEVA and sirolimus dissolved in tetrahydrofuran ("THF"), a solvent. Id. at ¶¶9, 11.

32. The base coat solution is sprayed onto the stent using a spraying device, similar to a spray gun. Id. at ¶11. Both the base coat solution and the spraying of the base coat solution are at room temperature. Id.

33. The stents are coated in a room where the normal room operating range is 17°C-24°C (64°F-76°F). Id. at ¶12; Ex. B at 10 to D.I. 68, Ex. 1 (Maryanoff Decl.). If the temperature in the coating facility drops below 15°C (60°F) or exceeds 26°C (80°F), the coating operation is "shut down." D.I. 68, Ex. 1 (Maryanoff Decl.) ¶12; Ex. B at 10 to D.I. 68, Ex. 1 (Maryanoff Decl.).

34. The sprayed stent is air dried for thirty minutes or more at room temperature. D.I. 68, Ex. 1 (Maryanoff Decl.) ¶13. This air drying process allows the solvent to evaporate, leaving the polymer/drug coating adhered to the stent at room temperature. Id.; see also D.I. 108, Ex. 2 Expert Report of Christopher Batich, Ph.D ("Batich Rpt.") ¶57 ("[d]uring the drying step, the solvent evaporates from the stent surface, leaving the polymers on the stent"); id. at ¶113 ("as the solvent evaporates from the stent, the polymers become adhered to the stent.").

35. The stent is then weighed to ensure that the FDA-approved amount of polymers and drug has adhered to the stent. D.I. 68, Ex. 1 (Maryanoff Dec.) ¶15. The stent weight would not be representative of the correct dosage of drug for patients if the polymer/drug coating had not adhered to the stent and did not remain adhered for the remainder of manufacture. Id. at ¶16. After being weighed, a top coat solution is applied over the polymer/drug coating. Id. at ¶17.

36. The top coat solution consists of PBMA dissolved in THF. Id. As with the base coat application, the top coat solution is at room temperature when it is sprayed onto the stent and the spraying occurs at room temperature. Id. at ¶18.

37. The stent is then sprayed with toluene. Like THF, toluene is a solvent for PBMA, PEVA and sirolimus. Both the toluene and the spraying of the toluene are at room temperature. After the toluene is sprayed onto the stent, the stent is allowed to air dry at room temperature. Id. at ¶19.

38. Once the air drying process is complete, the polymer/drug coating is adhered to the Cypher stent. Because the coating has dried and adhered at room temperature, it can be handled. Id. at ¶20.

39. The stents are then visually inspected and manicured if necessary with a sharp cutting tool to remove any irregularities or defects in the polymer/drug coating. The stents are then weighed again to determine if the polymer/drug coating on the stent conforms to FDA requirements. This step is critical to ensure that patients receive the correct dosage of drug. Id. at ¶¶22-24.

40. All coated stents that conform to the drug-content specifications are crimped (attached by reducing the stent diameter) under pressure on a balloon catheter that ultimately delivers the stent to the diseased vessel. Id. at ¶25.

41. MarcTec's expert, Dr. Batich, admits the entire coating process for the Cypher stent occurs at room temperature. D.I. 125, Ex. 3 (Batich Tr.) 156:17-22, 177:13-178:3, 209:3-20; see also id. at 154:13-155:2, 180:7-17.

ii. Sterilization

42. The stents are sterilized using a "low temperature ethylene oxide sterilization" process that was specially developed for Cordis's drug-containing products. Id. at ¶29; see also Ex. D at 1 to D.I. 68, Ex. 1 (Maryanoff Decl.).

43. Sirolimus is a sensitive drug and heat accelerates its degradation. Id. at D.I. 68, Ex. 1 (Maryanoff Decl.) ¶30. Accordingly, Cordis uses a low temperature sterilization process for Cypher. Id. at ¶31.

44. The stents are sterilized in a sterilization chamber set at 30°C-35°C (86°F-95°F). Id. at ¶31; see also Ex. D at 1 to D.I. 68, Ex. 1 (Maryanoff Decl.); D.I. 125, Ex. 3 (Batich Tr.) 148:20-22, 151:10-18.

45. Apart from the vacuum heating process used for stents sold in Japan, the sterilization process is the only time that the Cypher drug-eluting coating is exposed to temperatures above room temperature. D.I. 125, Ex. 3 (Batich Tr.) 152:2-14, 156:17-22; D.I. 68, Ex. 1 (Maryanoff Decl.) ¶33.

46. Sterilization is conducted to sterilize the product, not to cause the polymer/drug coating to adhere. D.I. 68, Ex. 1 (Maryanoff Decl.) at ¶34. Indeed, the

Cypher coating has adhered to the stent well prior to sterilization and, thus, prior to any exposure to the temperatures used during the sterilization process. Id.; see also D.I. 125, Ex. 3 (Batich Tr.) 94:9-23, 95:8-13, 155:3-156:8.

47. The temperatures used during sterilization do not cause the polymers in Cypher's drug-eluting coating (PBMA and PEVA) to change their state so as to flow or become tacky. D.I. 68, Ex. 1 (Maryanoff Decl.) ¶¶36, 39. Instead, the Cypher stent is sterilized at temperatures lower than the temperature in the human body, i.e. 37ºC (98.6 ºF), where the stent is used. Id. at ¶32; D.I. 125, Ex. 3 (Batich Tr.) 151:10-18 (agreeing that "in practice, during sterilization of Cypher drug-eluting stents for the last two years, the temperature during sterilization has never exceeded 35 degrees Celsius.").

48. Cypher would have to be exposed to temperatures above 62ºC (144ºF) for these polymers to change their state and become flowable and tacky. D.I. 68, Ex. 2 Declaration of Robson F. Storey, Ph.D. ("Storey Decl.") ¶7; D.I. 108, Ex. 2 (Batich Rpt.) ¶¶72-73, 75-76, 103-105, Ex. H. Dr. Batich found that PEVA had to be exposed to a temperature of 70ºC or above in order to become flowable, tacky and adherent due to heat. D.I. 125, Ex. 3, 107:6-12; see also D.I. 108, Ex. 2 (Batich Rpt.) ¶¶72-73, 103-105, Ex. H. The PEVA and PBMA polymers in Cypher's drug-eluting coating are never exposed to such temperatures. D.I. 125, Ex. 3 (Batich Tr.) 152:2-14 (agreeing that "the highest temperature during the Cordis manufacturing process that either the Cypher stent sold in the U.S. or the OUS markets are subjected to is 35 degrees Celsius" and that "the highest temperature that the Cypher stents designated for the

Japanese market are exposed to is 45, plus or minus 5 degrees Celsius."); see also D.I. 68, Ex. 1 (Maryanoff Decl.) ¶¶31, 33.

49. As a result, it is not scientifically possible for the polymers in Cypher to be bonded to the Cypher stent by the application of heat and, in fact, the polymers are not bonded to the Cypher stent by the application of heat. D.I. 114, Ex. 9 Rebuttal Expert Report of Robson F. Storey, Ph.D ("Storey R.Rpt.") at 33. They are applied and adhere to the stent at room temperature. D.I. 68, Ex. 1 (Maryanoff Decl.) ¶¶10, 13, 20-21; D.I. 125, Ex. 3 (Batich Tr.) 154:13-155:2, 156:17-22, 177:2-180:17, 209:3-20.

CONCLUSIONS OF LAW

I. Literal Infringement

1. Summary judgment is just "as appropriate in a patent case as in any other." ***Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984); *Nike, Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994)**.

2. "A determination of patent infringement requires a two-step analysis. The court must first interpret the claims to determine their scope and meaning. It must then compare the properly construed claims to the allegedly infringing device." ***PSC Computer Prods., Inc v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1357 (Fed. Cir. 2004) (citing *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc))**.

3. The first step is an issue of law for the court; the second step is an issue of fact. ***Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000)**. However, "[w]here the parties do not dispute any relevant facts regarding the accused product, . . . [and merely] disagree over possible claim interpretations, the question of literal infringement collapses into claim construction and is amenable to summary judgment." ***General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 983 (Fed. Cir. 1997)**.

4. The burden of proving patent infringement falls on the patentee. ***PSC*, 355 F.3d at 1357; *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001)**. The patentee must prove that "all of the elements of the [asserted] claim, as correctly construed, [are] present in the accused" product. ***TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1371 (Fed. Cir. 2002)**.

5. There are two types of patent claims: independent claims and dependent claims. It is "a fundamental principle of patent law that 'dependent claims cannot be found [to be] infringed unless the claims from which they depend have been found to have been infringed.'" ***Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1383 (Fed. Cir. 2000) (quoting *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989))**.

II. The Doctrine of Equivalents

6. An accused device that does not literally infringe may still be found to infringe under the doctrine of equivalents ("DOE") "if only 'insubstantial differences' distinguish the missing claim element from the corresponding aspects of the accused device." ***Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1423 (Fed. Cir. 1997)**.

7. "Whether equivalency exists may be determined based on the 'insubstantial differences' test or based on the 'triple identity' test, namely, whether the element of the accused device 'performs substantially the same function in substantially the same way to obtain the same result.'" ***TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1376 (Fed. Cir. 2008) (citation omitted)**.

8. As with literal infringement, the patentee bears the burden of proof on the DOE. ***PCS*, 355 F.3d at 1357**.

9. The DOE cannot be used to recapture structures "specifically excluded" from the scope of the claims during claim construction. ***Decisioning.com, Inc., v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1315 (Fed. Cir. 2008) (collecting cases)**.

10. Prosecution history estoppel bars the assertion of the DOE when (1) the patentee clearly and unmistakably surrenders subject matter by arguments made to the examiner (argument-based estoppel) or (2) makes a narrowing amendment for

purposes of patentability (amendment-based estoppel). ***Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002); *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376 (Fed. Cir. 1999)**.

11. Argument-based estoppel precludes a patentee from obtaining the equivalent for subject matter relinquished during prosecution. ***Pharmacia*, 170 F.3d at 1376; *Bayer*, 212 F.3d at 1253**. The arguments must evince a clear and unmistakable surrender of subject matter in order for there to be an estoppel. ***Pharmacia*, 170 F.3d at 1377; *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1359 (Fed. Cir. 2000)**.

12. Amendment-based estoppel precludes application of the DOE where an amendment is made for reasons of patentability and narrows the scope of the claim. ***Festo Corp.*, 535 U.S. at 727; *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003) (en banc)**.

13. Once it has been determined that the narrowing amendment has been made for a reason related to patentability, it is presumed that "the patentee has surrendered all territory between the original claim limitation and the amended claim limitation." ***Festo*, 344 F.3d at 1367; *Festo*, 535 U.S. at 740**.

III. Role of Expert Testimony

14. "Under modern summary judgment law, a patentee who fails to provide probative evidence of infringement runs the risk of being peremptorily nonsuited." ***Novartis*, 271 F.3d at 1050-51 (citing *Celotex Corp. v. Catrett*, 477 U.S. 317,**

322-23 (1986)). "[A] party does not meet this evidentiary threshold merely by submitting the affidavit of an expert who opines that the accused device meets the claim limitations." ***Novartis*, 271 F.3d at 1051**.

15. "It is well settled that an expert's unsupported conclusion on the ultimate issue of infringement is insufficient to raise a genuine issue of material fact, and that a party may not avoid that rule simply by framing the expert's conclusion as an assertion that a particular critical claim limitation is found in the accused device." ***Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1278 (Fed. Cir. 2004)); *see also Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1112 (Fed. Cir. 2000) (finding conclusory declarations alleging infringement of accused devices insufficient to carry patentee's burden of proving infringement, both literally and under the doctrine of equivalents); *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1317 (Fed. Cir. 1999) (same); *Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 876 (Fed. Cir. 1998) (same)**.

16. Rather, "the expert must set forth the factual foundation for his opinion . . . in sufficient detail for the court to determine whether that factual foundation would support a finding of infringement under the claim construction adopted by the court, with all reasonable inferences drawn in favor of the nonmovant." ***Novartis*, 271 F.3d at 1051 (quoting *Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1047-48 (Fed. Cir. 2000))**.

17. Expert opinions under an incorrect claim construction have no relevance. ***PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1246 (Fed. Cir. 2002); *Liquid Dynamics Corp. v. Vaughan Co.*, 2004 WL 2260626, at *4-5 (N.D. Ill. Oct. 1, 2004) (excluding expert testimony that did not conform to the correct claim construction)**. Such evidence does not assist the trier of fact and is inadmissible.

IV. The Cypher Stent Does Not Meet the Claim Terms Requiring a Surgical Implant and a Device at Least a Portion of Which is Expandable

18. All of the asserted claims of the '290 patent require "an implant" for implantation in a human body. All of the asserted claims of the '753 patent require "a surgical device" for implantation in a body.

19. Under the Court's construction of these claim terms stents, are excluded from the scope of the claims, D.I. 175 at 19, and the Cypher stent cannot infringe either patent as a matter of law. ***See, e.g., K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1366-69 (Fed. Cir. 1999) (affirming grant of summary judgment of no literal infringement where the only issue is claim construction); *General Mills*, 103 F.3d at 983-85 (same)**.

A. Cypher is a Stent, Not a Surgical Device

20. The terms "a surgical device" from claim 1 of the '753 patent and "an implant" from claim 1 of the '290 patent have both been construed to mean "a device for use in surgical applications, but not including an expandable intraluminal vascular graft or expandable prosthesis for a body passageway." D.I. 175 at 19.

21. Under this claim construction, "expandable intraluminal vascular grafts," *i.e.*, stents, are excluded from the scope of the claims because Dr. Bonutti disclaimed such devices in order to obtain allowance of his patents. *Id*. at 9-10, 16.

22. MarcTec does not dispute that Cypher is a stent. Rather, it contends that stents are covered by the claims even though the Court construed the terms "surgical implant" and "implant" to exclude the "expandable intraluminal vascular grafts" that Dr. Palmaz disclosed and Dr. Bonutti disclaimed. D.I. 108 at 9-12; *see also* MarcTec's Responses to Defendants' Proposed Findings of Fact and Conclusions of Law and Counter-Statement of Facts in Support of MarcTec's Opposition to Defendants' Motion for Summary Judgment ("Pl. Resp.") at page 30.

23. MarcTec contends that Dr. Palmaz's "expandable intraluminal vascular graft" and "expandable prosthesis for a body passageway" is not a stent. D.I. 108 at 11-12; *see also* Pl. Resp. at page 30. MarcTec also claims that an "expandable prosthesis for a body passageway" supposedly is "*not* for inclusion in a blood vessel, and thus cannot be a coronary stent." D.I. 108 at 12 n.11; Pl. Resp. at page 31. This mischaracterizes Dr. Palmaz's invention, and is in conflict with admissions from MarcTec's own witnesses.

24. MarcTec's expert cardiologist, Dr. Denardo, admits that "just like a coronary stent, both the intraluminal vascular graft and the expandable prosthesis of the '417 patent can be used in a blood vessel." D.I. 125, Ex. 2 (Denardo Tr.) 84:2-10; *see also id*. at 78:21-79:16, 83:8-23.

25. As already recognized by the Court, Dr. Palmaz, the inventor of the balloon-expandable stent, used the terms "intraluminal vascular graft" and "expandable prosthesis" in the '417 patent to refer to his invention of the balloon-expandable stent. D.I. 175 at 9, 16.

26. The Federal Circuit and other district courts have recognized that the device disclosed in the Palmaz '417 patent (and in the Palmaz 4,739,762 patent ("'762 patent") from which it claims priority), which was disclaimed by Dr. Bonutti during the prosecution of the patents-in-suit, is a stent. ***E.g.*, *Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1162 (Fed. Cir. 2008) ("The [Palmaz] '762 patent discloses a coronary stent."); *Advanced Cardiovascular Sys. v. Medtronic Vascular, Inc.*, 485 F. Supp. 2d 538, 550 (D. Del. 2007) (Robinson, J.) ("Palmaz' 417 discloses a stent."); *Medinol Ltd. v. Guidant Corp.*, 341 F. Supp. 2d 301, 305 (S.D.N.Y. 2004) (Scheindlin, J.) ("Palmaz patented a stent (Palmaz '417 Patent).")**.

27. Figures 1A and 1B of the Palmaz '762 (D.I. 70, Ex. E) and '417 patents (D.I. 70, Ex. G) "show the disclosed stent in its collapsed (Fig. 1A) and expanded (Fig. 1B) forms," ***Cordis*, 511 F.3d at 1163**, and this stent is for inclusion in a blood

vessel. D.I. 70, Ex. G at Abstract ("intraluminal vascular grafts are expanded within a blood vessel by an angioplasty balloon … to dilate and expand the lumen of a blood vessel"), *see also id*. at 5:26-35, 6:46-54.

28. "MarcTec admits that the Cypher drug-eluting stent would not meet 'a surgical device for implementation in a body' of claim 1 of the '753 patent and 'an implant for implantation in a human body' of claim 1 of the '290 patent based on the Court's constructions and additional factual findings." Pl. Resp. at page 33.

29. Cypher is a stent. As such, it cannot infringe either the '753 patent or the '290 patent under the Court's claim construction. "Literal infringement requires that each and every limitation set forth in a claim appear in an accused product." ***V-Formation, Inc., v. Benetton Group SpA*, 401 F.3d 1307, 1312 (Fed. Cir. 2005)**.

B. The Cypher Stent is Fully Expandable From End-to-End

30. All of the asserted claims of the '753 patent require "an implant, at least a portion of which is expandable." Similarly, all the asserted claims of the '290 patent require that "at least a portion of the tubular member has a second cross sectional size . . . larger than the first cross sectional size . . . to thereby lock the tubular member against tissue in the human body."

31. The Court has construed the phrase "an implant, at least a portion of which is expandable" from claim 1 of the '753 patent to mean that "a portion, but not all of the implant, is expandable." D.I. 175 at 20.

32. Similarly, the Court has construed the phrase "a tubular member . . . mechanically expandable . . . from a contracted condition . . . to an expanded

condition in which at least a portion of the tubular member has a second cross sectional size . . . larger than the first cross sectional size to thereby lock the tubular member against tissue in the human body" from claim 1 of the '290 patent to mean that "a portion, but not all, of the tubular member is expandable so that when expanded, its cross-sectional size is larger than its initial cross-sectional size. The expansion of only a portion of the tubular member enables it to be locked against tissue." *Id.*

33. Because these constructions properly limit the language "at least a portion" to at least "a portion, but not all [of the device]," neither of the patents-in-suit can cover devices that expand in their entirety from end-to-end. *Id.*

34. MarcTec misreads the Court's construction as requiring expansion in both the radial and longitudinal directions. D.I. 108 at 12-13; Pl. Resp. at pages 34-35. This is incorrect. As seen in claim 1 of the '290 patent, the relevant expansion is in the radial direction, such that "at least a portion of the tubular member has a second cross sectional size in a plane perpendicular to the longitudinal central axis of the tubular member." There is no requirement of longitudinal expansion in the claim language or in the Court's construction of that language.

35. MarcTec's medical expert concedes that Cypher is expandable along its entire length, from one end to the other. D.I. 125, Ex. 2 (Denardo Tr.) 174:24-175:7 (agreeing that "the diameter of the Cypher stent increases along its entire length once it's balloon-expanded."); *see also* Pl. Resp. at page 35. Indeed, "MarcTec [itself]

admits that the Cypher stent expands in its entirety in the radial direction." Pl. Resp. at page 8.

36. The Court's construction requires expansion of a "portion, but not all" of the device and excludes devices where the device expands along its entire length. D.I. 175 at 20. As the Court previously found, a stent is a "fully expandable device." *Id.*

37. Because the Cypher stent is expandable in its entirety from end-to-end, and indeed must be fully expanded to work, no reasonable juror could find infringement of either patent under the Court's claim construction.

V. The Cypher Coating Does Not Meet the Heat Bonding Claim Terms

38. All of the asserted claims require that the polymeric or heat bondable material must (1) be non-flowable and non-adherent at room temperature, (2) be bonded to the implant or tubular member, and (3) become flowable, tacky and adherent upon the application of heat. These terms, separately and together, require the use of heat to bond the polymer coating to the device. In particular, polymer coatings are excluded when, as in the Cypher stent, they adhere at room temperature. Rather, heat must be applied to cause the bond, and the heat must be such as to cause the otherwise non-adhering polymers to change state and become flowable, tacky and adherent upon the application of heat. That is, heat must transform the material from one state to the opposite state (i.e., from being non-flowable and non-adherent at room temperature to being flowable and adherent upon the application of heat).

39. Under the Court's construction of these terms, MarcTec cannot prove that the Cypher stent meets any of these limitations. Summary judgment of no literal infringement is therefore appropriate. ***See, e.g., K-2 Corp.*, 191 F.3d at 1366-69 (affirming grant of summary judgment of no infringement); *General Mills*, 103 F.3d at 983-85 (same)**.

A. The Cypher Coating Adheres at Room Temperature

40. As construed by the Court, the phrase "non-flowable and *non-adherent at room temperature*," means that the polymeric material (the '753 patent) and the heat bondable material (the '290 patent) cannot flow at room temperature and cannot adhere if placed on the device at room temperature. D.I. 175 at 27-28. Both requirements must be met for the claim to be infringed. ***V-Formation*, 401 F.3d at 1312**.

41. Undisputed evidence establishes that the polymers in Cypher's drug-eluting coating adhere to the stent at room temperature. Room temperature polymer solutions are sprayed onto the stent at room temperature. D.I. 68, Ex. 1 (Maryanoff Decl.) ¶¶ 8, 10, 12, 18. The stents are then air dried at room temperature. *Id*. at ¶¶ 13, 19. This air drying process allows the solvent to evaporate, leaving the polymers and drug adhered to the stent at room temperature. *Id.* at ¶¶9-10, 13, 20.

42. MarcTec's only expert on the ultimate issue of infringement, Dr. Batich, agreed that "the PEVA and PBMA polymers adhere to the Cypher stent at room temperature." D.I. 125, Ex. 3 (Batich Tr.) 208:22-209:2. He agreed that "PEVA and

PBMA polymers are applied to the stent at room temperature," that "the solution that they're applied in is at room temperature," and that "you get some adhesion of PEVA and PBMA to the Cypher stent at room temperature." *Id.* at 209:3-20; *see also id.* at 154:13-154:2, 156:17-22, 177:9-178:3.

43. With the evidence being undisputed on the relevant issue, MarcTec focuses on the use of a solvent during manufacture to excuse the fact that the polymers in the Cypher stent adhere at room temperature. D.I. 108 at 16-17, n.13; D.I. 108, Ex. 2 (Batich Rpt.) ¶100 ("When Defendants dissolve PEVA and PBMA in THF, that substance is no longer the polymeric material alone, but has become a solution of polymeric material and solvent."); Pl. Resp. at page 39 (same). MarcTec's argument is incorrect. First, neither the claims nor the Court's construction requires the presence or absence of other materials (such as solvent). Moreover, Dr. Batich's own admissions demonstrate that the polymers themselves adhere to the stent.

44. Dr. Batich readily admits that the polymers, not the solvent, adhere to the stent. In fact, the polymers adhere to the stent once the solvent evaporates, leaving the polymers behind.

> During the drying step, the solvent evaporates from the stent surface, leaving the polymers on the stent. It is after the THF evaporates that the polymers adhere to the stent.

(D.I. 108, Ex. 2 (Batich Rpt.) ¶57).

> [A]s the solvent evaporates from the stent, the polymers become adhered to the stent.

(*Id.* at ¶113).

45. In addition, Dr. Batich's own testing shows that the polymers adhere at room temperature after the solvent, THF, evaporates.

> Q. And the PBMA coating adhered to the metal strips at room temperature when the THF evaporated, correct?
>
> A. Yes.

D.I. 125, Ex. 3 (Batich Tr.) 124:7-10. Dr. Batich observed that this adherence occurred at room temperature after only thirty seconds of air drying. *Id.* at 124:1-10. This is precisely how solution casting works. Polymers are applied in solution and adhere to the substrate of interest at room temperate when the solvent evaporates. D.I. 68, Ex. 1 (Maryanoff Decl.) ¶¶8-10; D.I. 114, Ex. 9 (Storey R.Rpt.) at 8.

46. Finally, MarcTec tries to change the frame of reference by asserting that the raw polymers do not "stick[] to the glass, to spatulas, or to anyone's hand" and that "the final product does not adhere to external sources such as instruments or hands at room temperature." D.I. 108 at 6, 8 and 17; *see also* Pl. Resp. at pages 39-41, 63. This is irrelevant. Under the Court's construction of the disputed claims, the issue is not whether the polymers adhere at room temperature to glass or spatulas or skin; rather, the issue is whether they adhere to the accused device. D.I. 175 at 27-28. The evidence on that issue is undisputed. D.I. 125, Ex. 3 (Batich Tr.) 209:3-20, 95:8-20, 177:9-178:3, 180:7-17.

47. Because the polymers adhere to the accused device at room temperature, the asserted claims of the '753 and '290 patents do not cover the Cypher stent.

B. The Cypher Coating is Not Bonded By Heat

48. All of the asserted claims require a material to be bonded to the device. The claims of the '753 patent require "a polymeric material *bonded* to the implant" and the claims of the '290 patent require "a first component *bonded* to at least a portion of the tubular member."

49. The Court has construed these claim terms as requiring that the material is bonded to the implant or tubular member "by the application of heat." D.I. 175 at 26. This construction requires that the heat applied to the polymers must cause the bond, not simply facilitate the bonding process.

50. Testing by Cordis's expert, Dr. Storey, showed that the Cypher drug-eluting coating would have to be exposed to temperatures above 62°C (144°F) to observe flow, tackiness or adherence due to heat. D.I. 68, Ex. 2 (Storey Decl.) ¶7. MarcTec's expert Dr. Batich showed that the polymers used in the Cypher stent would need to be heated to temperatures above 70°C (158°F) in order to become flowable, tacky or adherent by the application of heat so as to bond to the device. D.I. 108, Ex. 2 (Batich Rpt.) ¶¶72-73, 75-76, 103-105, Ex. H; D.I. 125, Ex. 3 (Batich Tr.) 107:6-20.

51. It is undisputed that the polymers in Cypher's coating are never exposed to such temperatures. D.I. 125, Ex. 3 (Batich Tr.) 152:2-14 (agreeing that "the

highest temperature during the Cordis manufacturing process that either the Cypher stent sold in the U.S. or the OUS markets are subjected to is 35 degrees Celsius" and that "the highest temperature that the Cypher stents designated for the Japanese market are exposed to is 45, plus or minus 5 degrees Celsius."). The polymers in the Cypher coating are applied to the device by spraying at room temperature and bond to the device at room temperature. As Dr. Batich admits, the "entire coating process occurs at room temperature." D.I. 125, Ex. 3 (Batich Tr.) 156:17-22; *see also id*. at 177:9-178:3, 209:3-20. Moreover, because the polymers in Cypher's drug-eluting coating are not exposed to temperatures above 62°C or 70°C, it is not possible for the polymers to be bonded to the Cypher stent by the application of heat. D.I. 114, Ex. 9 (Storey R.Rpt.) at 33; D.I. 125, Ex. 3 (Batich Tr.) 107:6-20.

52. MarcTec mischaracterizes the claim construction adopted by the Court as merely requiring the use of heat to "facilitate the bonding of the polymeric material to the stent." D.I. 108, Ex. 2 (Batich Rpt.) ¶49 ("[d]efendants' proposed construction apparently requires the application of heat to facilitate the bonding of the polymeric material to the stent."); D.I. 125 Ex. 3 (Batich Tr.) 170:7-12 (same). This is incorrect. Consistent with what Dr. Bonutti actually invented, the Court's claim construction requires that heat applied to the polymers must cause the bond. D.I. 175 at 25-26. As this Court has held, Dr. Bonutti's amendments "made clear that Dr. Bonutti's invention required the application of heat to a heat bondable material to cause that material to transform from one state (non-flowable and non-adherent) to a different state (flowable, tacky and adherent)." *Id*. at 11; *see also id.* at 23 (Dr.

Bonutti's argument "limits his claims so as to exclude devices where a material is bonded to the device other than by the application of heat"); *id.* at 28 ("It takes heat to bond in the Bonutti invention and that heat must be sufficient to cause the material to be bonded to become flowable, tacky and adherent."); *see also* D.I. 70, Ex. A ('753 patent) at 1:66-2:18.

53. Under its incorrect "facilitation" standard, MarTec relies on any step that involves heat regardless of what, if anything, is being heated and whether it causes the polymers to bond to the device. D.I. 108 at 14-16; Pl. Resp. at pages 16-17; D.I. 108, Ex. 2 (Batich Rpt.) ¶¶49-65. Such evidence is not premised on the correct judicial claim construction and has no relevance to Cordis's motion. ***PIN/NIP*, 304 F.3d at 1246 (arguments addressing an incorrect construction have no relevance)**. As MarcTec admits "'[c]omparisons based on an incorrect claim construction have no relevance and cannot aid the fact finder.'" D.I. 117 at 4.

54. The undisputed facts establish that Cypher does not infringe under the Court's claim construction. Cypher's polymers are applied to the device at room temperature and bond to the device at room temperature. Plaintiff's expert Dr. Batich admits that the coating process occurs at room temperature and that heat is not applied to the polymers. D.I. 125, Ex. 3 (Batich Tr.) 156:17-158:6, 177:9-178:3, 209:3-20.

> Q: [A]re you aware of any evidence, whether tests or literature showing an increase in temperature above room temperature throughout the entire period from the

> application of the base coat solution through final weighing of a coated Cypher stent?
>
> A: I am not aware of any experimental evidence showing any increase in temperature over the – that part of the coating process.

(*Id*. at 180:7-17 (objection omitted)).

55. MarcTec's expert, Dr. Batich, relies on an untested prediction by another MarcTec expert, Dr. Sojka, that spraying droplets at unrealistically high speeds will increase their temperature by 0.45-18°C depending on the size of the droplet and that spraying the smallest hypothetical droplet at "maximum velocity" would increase its temperature (from room temperature, 17-24°C, to 35-42°C) for an infinitesimally short period of time (five millionths of a second). D.I. 108 at 15; Pl. Resp. at pages 10, 17, 63-64; D.I. 115, Ex. 4 Expert Report of Paul E. Sojka, Ph.D. ("Sojka Rpt.") at 5-6; D.I. 125, Ex. 4 (Sojka Tr.) 136:4-8, 163:17-23; 185:15-186:4.

56. MarcTec's experts did not test Dr. Sojka's theory and could not identify any tests or publications supporting his untested predictions. D.I. 125, Ex. 4 (Sojka Tr.) 72:15-74:9, 99:23-100:21; D.I. 125, Ex. 3 (Batich Tr.) 163:16-164:1, 165:24-166:4. In his deposition, Dr. Sojka admitted that the five millionths of a second (0.000005) period that his prediction is limited to is a period so infinitesimally brief his predicted temperature increase has not been and cannot be experimentally tested or verified. D.I. 125, Ex. 4 (Sojka Tr.) 58:18-59:3, 163:6-23.

57. Dr. Sojka admitted that he is not aware of any instrumentation that could detect an increase in temperature in the fleeting 0.000005-second interval that is the subject of his opinion. *Id*. at 161:11-162:1 ("I know of no equipment that would be available to detect the temperature of a drop impacting a surface in that 5-microsecond interval."); *see also id.* at 35:9-36:4 ("[t]emperature-measuring equipment typically cannot respond to anything like that time interval"); *id.* at 162:12-163:5 ("we don't have techniques that will measure the temperature of the – of the substance that contained in the drop for that – for the 5 microseconds that each individual drop impacts the surface, not that I know of"); *id.* at 163:6-16 ("I don't know of a technique that could be – that could be used to measure the temperature increase of that substance, the substance that is in the drop, in a roughly 5-microsecond time period.").

58. Dr. Sojka had no opinions on any increase in temperature that is capable of being measured or tested. Thus, he had no opinions on whether there was any increase in temperature before or after the 0.000005 second interval, *id*. at 185:15-186:4, and had no opinions on whether spraying would result in any increase in the surface temperature of the Cypher stent itself. *Id*. at 36:24-37:10, 56:10-13.

59. Dr. Sojka's theories are also contrary to everyday experience. If spraying a fluid on a surface automatically increased its temperature, a cold shower would feel hot, not cold. As MarcTec's experts admit, this is not the case. D.I. 125, Ex. 3 (Batich Tr.) 165:6-17; D.I. 125, Ex. 4 (Sojka Tr.) 168:16-169:3.

60. Dr. Sojka also based his untested and untestable predictions on extreme conditions that are not related to the Cypher manufacturing process. Dr. Sojka admitted that he did not know anything about the Cordis spray process, including the actual droplet velocities. D.I. 125, Ex. 4 (Sojka Tr.) 85:14-16, 106:5-110:20. Although he assumed that the droplets used during spraying would travel at speeds up to ¾ the speed of sound (248 meters per second or 575 m.p.h.), Dr. Sojka was not aware of a spraying process for any medical device that causes droplets to move at anything approaching this speed. *Id.* at 79:18-80:7, 94:14-18.

61. Dr. Sojka has published papers in which he has described the use of available equipment to measure the velocity of droplets in a spray. D.I. 114, Ex. 3 (Sojka Tr.) 39:6-23. In these studies what he found is that the droplets move at speeds of only 1.5-to-3.5 meters per second – a small fraction of the 248 meters per second that he assumed here. *Id.* at 175:2-24.

62. Dr. Sojka's theory that spraying droplets at an unrealistic speed, approaching the speed of sound (and unrelated to anything that happens in the Cypher coating process) would increase the temperature of the droplets – in ways that cannot be measured – for 5 millionths of a second (0.000005 seconds) is an untested and untestable theory that is neither reliable not relevant to the issues at hand. Dr. Sojka's testimony, accordingly, is inadmissible under ***Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993)** and **FEDERAL RULE OF EVIDENCE ("FRE") 702.**

63. Dr. Sojka did not know what heat bonding was, D.I. 125, Ex. 4 (Sojka Tr.) 70:1-9, and had no opinions concerning adhering polymers to a surface. *Id*. at 102:4-7. Dr. Batich relied upon Dr. Sojka's untested prediction to conclude that spraying somehow "facilitates" the bonding of one polymer, PBMA, to Cypher. D.I. 108, Ex. 2 (Batich Rpt.) ¶¶51, 56. MarcTec offered no evidence to support Dr. Batich's speculation that an increase in the temperature of polymer droplets that lasts only five millionths of a second – even if real – would allow PBMA to bond to the device.

64. Dr. Batich's opinions concerning spraying also are predicated on an assumption that PBMA will bond to the Cypher stent at 35°C. D.I. 108, Ex. 2 (Batich Rpt.) ¶56. Dr. Batich claims to have observed some adhesion at 35ºC when using a 2.3 kg weight that the PBMA in Cypher is never subjected to. *Id*.; D.I. 125, Ex. 3 (Batich Tr.) 182:2-184:6. In its manufacturing process, Cordis does not use a 2.3 kg weight – or any other weight – to press the polymers onto the device. D.I. 125, Ex. 3 (Batich Tr.) 183:1-4, 143:7-10, 147:23-148:6. Indeed, Dr. Batich admitted that placing a 2.3 kg weight on top of a Cypher stent "would destroy the product." *Id*. at 143:21-144:1. As discussed further below, Dr. Batich's experiment was performed under extreme experimental conditions unrelated to the actual manufacture of the Cypher stent, and testimony concerning this test is inadmissible under ***Daubert*** and **FRE 702**. ***See also In re: Silicone Gel Breast Implants Products Liab. Litig.*,**

318 F. Supp. 2d 879, 902-03 (C.D. Cal. 2004) (Matz, J.) (excluding testing by Dr. Batich in another case because he employed "extreme" conditions).

65. Cordis's expert Dr. Atwood conducted a simple experiment to test MarcTec's hypothesis that spraying THF increases temperature. He sprayed THF on a thermistor (a device used to detect temperature change). The results showed that spraying cooled the thermistor over a period of seconds, rather than heating it. D.I. 114, Ex. 8, Expert Report of Professor Jerry L. Atwood, Ph.D. ("Atwood Rpt.") ¶¶61-63; D.I. 125, Ex. 4 (Sojka Tr.) 152:9-153:23. His experiment provides uncontradicted empirical evidence that spraying does not cause an increase in temperature above room temperature. Dr. Batich "believe[s] [Dr. Atwood's] results" and is "not aware of any experimental tests conducted by or on behalf of MarcTec showing that spraying THF will cause an increase in temperature." D.I. 125, Ex. 3 (Batich Tr.) 162:12-163:20. Dr. Sojka also admitted that he did not "have any reason to question the validity of [Dr. Atwood's] measurements." D.I. 125, Ex. 4 (Sojka Tr.) 154:16-17.

66. Although MarcTec's experts do not dispute Dr. Atwood's findings (*i.e.*, that spraying of THF results in a decrease in temperature over a period of seconds), MarcTec argues that Dr. Atwood's findings do not refute Dr. Sojka's untested prediction. Pl. Resp. at page 45. This is because Dr. Sojka's opinion is limited to a supposed temperature change that lasts only .000005 seconds – a period so brief that no instrument can measure it, whereas Dr. Atwood investigated a measurable effect – the effect of spraying THF on the "order of seconds." D.I. 125, Ex. 4 (Sojka

Tr.) 152:24-153:23. Dr. Sojka's opinion is untestable and contrary to anything which can be measured and tested, such as Dr. Atwood's demonstration that the spraying of THF does not increase temperature. Dr. Sojka's spraying theory is inadmissible for this and the other reasons discussed above.

67. MarcTec also attempts to equate evaporation of solvent with heating. D.I. 108 at 15; Pl. Resp. at pages 15, 17. If evaporation of THF caused heating, then Dr. Atwood's study would have shown an increase in temperature. But as discussed above, it showed the exact opposite. Again, this is not surprising. Everyday experience tells us that natural evaporative cooling, perspiration, cools the human body rather than heats it. D.I. 125, Ex. 3 (Batich Tr.) 166:5-10; Ex. 4, Sojka Tr. 129:3-10. Indeed, Dr. Batich admitted at his deposition that evaporation will not increase the temperature of the polymers. D.I. 125 Ex. 3 (Batich Tr.) 167:11-14.

> Q. Does the evaporation of THF increase the temperature of PEVA and PBMA?
>
> A. I don't think the evaporation process would increase their temperature.

68. In short, MarcTec cannot show any use of heat when the polymers are being applied to the device and bond to it. Instead, it argues that heat is used earlier or later in Cypher's manufacturing process. D.I. 108 at 14-16; Pl. Resp. at pages 16-18, 63-65. Neither has any bearing on whether the polymers are bonded to the device by the application of heat. Dr. Batich's testimony that such steps "facilitate" bonding (D.I. 108, Ex. 2 (Batich Rpt.) ¶¶49-65) does not address the requirements

of the Court's claim construction and is irrelevant to the question of infringement. It is also inadmissible under ***Daubert***.

69. Manufacturing steps that occur *before* the Cypher coating is applied cannot bond the polymers to the stent. For example, MarcTec points out that heat is used to cure silane and crack the precursor to Parylene C (paracyclophane dimer), which is used to coat the stent before the PEVA and PBMA polymers are applied, and to anneal Parylene C for the Japanese product. D.I. 108 at 14-15; Pl. Resp. at pages 16-17, 63. But this heat is not applied to PEVA or PBMA, the polymers in Cypher's drug-eluting coating. It is undisputed that those polymers are applied at room temperature to a room-temperature Parylene-C coated stent. D.I. 125, Ex. 3 (Batich Tr.) 154:10-155:2 (agreeing that the room temperature "solution is applied by spraying [] a room temperature, parylene C-coated stent" and that there is no "reason to believe that [a] stent sitting in the room temperature environment is at anything other than room temperature") *id.* at 209:3-9 (agreeing that "PEVA and PBMA polymers are applied to the stent at room temperature" and that "the solution that they're applied in is at room temperature.").

70. MarcTec's reliance on solution preparation (D.I. 108 at 6-7; Pl. Resp. at pages 10-11, 16-17, 63) is similarly misplaced. Cordis uses temperatures of 32°C or below to dissolve PEVA and PBMA in solvent, but this is irrelevant to the question of infringement. Once the polymers are dissolved, the solution is lowered to room temperature and stored for up to 10 days at room temperature. D.I. 125, Ex. 3 (Batich Tr.) 154:3-12. Only then is the polymer solution applied and the polymers

bonded at room temperature to a room temperature stent. *Id*. at 154:3-155:2, 209:3-20.

71. In addition, temperatures of 32°C and below are nowhere near 70°C and above, the temperature that MarcTec's expert, Dr. Batich, agrees is necessary for PEVA or PBMA polymers to become flowable, tacky and adherent due to heat, and, thus, to bond. *Id*. at 107:6-20. Dr. Batich also agreed that the polymers will adhere to the stent whether the solutions are warmed or not; warming the solution only impacts how quickly the polymers dissolve during solution preparation. *Id*. at 117:8-118:10.

72. Finally, Dr. Batich admitted that, just as for the silane and Parylene C steps, solution preparation occurs prior to the application of the PEVA and PBMA polymers to the stent and cannot bond the polymers to the stent (*id*. at 153:18-154:2):

> Q. And all of those steps – silane, parylene C deposition and solution making – precede the application of PEVA and PBMA polymers to the stent, correct?
>
> A. Yes.
>
> Q. And you'll agree with me that PEVA and PBMA cannot be bonded to the stent before they're even applied to the stent, correct?
>
> A. Correct.

In arguing to the contrary, MarcTec simply ignores the testimony of its own expert. Pl. Resp. at page 46. It never explains how steps that occur long before the polymers

are applied to the stent at room temperature can bond the polymers to the stent by the application of heat.

73. Manufacturing steps that occur *after* the Cypher coating is adhered to the stent, such as sterilization and vacuum heating, are equally irrelevant. Based on his lap-shear test (where he measured some adhesion of PBMA to itself at 35ºC when using a 2.3 kg weight), Dr. Batich claims that PBMA will undergo "additional bonding" at the temperatures used during these steps. D.I. 108, Ex. 2 (Batich Rpt.) ¶¶58, 64. Not only is "additional bonding" of already bound polymers not at issue under the properly construed claims, but as discussed below, opinions predicated on Dr. Batich's extreme and unrealistic lap-shear test are of no relevance to the Cypher stent and are excluded under ***Daubert*** and **FRE 702**.

74. Moreover, as Dr. Batich admits, sterilization (as well as vacuum heating for stents sold in Japan) takes place after the polymers have adhered to the stent. D.I. 125, Ex. 3 (Batich Tr.) 155:3-156:2. Such steps cannot be the cause of the bonding to the device that has already occurred. Dr. Batich also admitted that he has "no experimental evidence" that the polymers adhere to the device any better after sterilization and vacuum heating than before them and that he has "done no experiments" to evaluate the adherence of the polymers to the device before versus after these events. *Id*. at 156:4-16; *see also id*. at 94:9-95:2. MarcTec's arguments to the contrary are only premised on Dr. Batich's extreme lap-shear test and ignore the admissions of its own expert. Pl. Resp. at pages 47-48.

75. It is not surprising that MarcTec has no evidence that these steps increase adhesion. The vacuum heating and sterilization steps occur at or below 45ºC±5°C and 35ºC, respectively, well below the 70ºC threshold that Dr. Batich identified as necessary for PEVA or PBMA to become flowable, tacky and adherent due to heat and thus, to bond. D.I. 108, Ex. 2 (Batich Rpt.) ¶¶ 72-73, 75-76, 103-105, Ex. H; D.I. 125, Ex. 3 (Batich Tr.) 107:6-20.

76. Dr. Batich has failed to provide any "valid scientific connection" between the use of heat in manufacturing steps that occur before or after the polymers are bonded to the stent and any fact in dispute. ***Daubert*, 509 U.S. at 591-92**. Dr. Batich's opinion is thus inadmissible under ***Daubert*** and **FRE 702**.

77. Moreover, Dr. Batich's own testing demonstrates that these manufacturing steps do not cause the polymers to bond to the stent. Dr. Batich dissolved PBMA in THF solvent at "room temperature." D.I. 108, Ex. 2 (Batich Rpt.) Ex. G. He then dipped aluminum foil strips (metal substrate) into this PBMA/THF and allowed them to "air dry." *Id*. The THF evaporated within "30 seconds," leaving a coating of PBMA polymer bonded to the metal strips. *Id*.

78. For this experiment, Dr. Batich did not warm the PBMA/THF solution. He did not use silane or Parylene C. He did not spray the PBMA/THF solution. He also did not sterilize the strips or subject them to vacuum heat at 45°C±5°C. Despite the absence of these steps, Dr. Batich acknowledged that the polymer bonded to the metal strips at room temperature within 30 seconds. *Id*; D.I. 125, Ex. 3 (Batich Tr.) 123:14-125:15. His experiment shows that the steps MarcTec cites are not what

causes the polymers to bond. If these steps were needed for bonding, the polymers would not bond in absence of any of them. Dr. Batich's experiment shows the opposite – that the polymers bond whether these steps occur or not.

79. In sum, heat is not used to make the polymers in Cypher's drug-eluting coating bond to the stent. As the Court previously explained, the Cypher stent has "a drug-eluting adhered by solution casting, not heat bonding." D.I. 175 at 13. The Court has also construed all of the asserted claims to require heat bonding. D.I. 175 at 22-26. The Cypher stent therefore does not infringe any of the asserted claims and no reasonable juror could find otherwise.

C. The Cypher Coating is Not Made Flowable, Tacky and Adherent By Heat

80. All of the asserted claims of the '753 patent require "a polymeric material . . . wherein the polymeric material . . . becomes flowable, tacky, and adherent upon the application of heat." The asserted claims of the '290 patent have the same requirement for the heat bondable material, *i.e.*, "a heat bondable material . . . wherein the heat bondable material . . . becomes flowable, tacky, and adherent upon the application of heat."

81. As construed, this language requires that the heat bondable or polymeric material is bonded to the implant or tubular member by the application of heat sufficient to cause the heat bondable material to become flowable, tacky and adherent. D.I. 175 at 28-29.

82. As the Court previously explained, the asserted claims describe a dichotomy between the state of the polymeric and heat bondable material before and after the application of heat. At room temperature (*i.e.*, before the application of heat) the polymeric material and heat bondable material are non-flowable and non-adherent. Those materials are only transformed to become flowable, tacky and adherent upon the application of heat. *Id*. at 28.

83. Cypher's coating does not undergo that transformation. It has already adhered to the stent at room temperature due to the application of solvent, not heat. Moreover, after the Cypher coating has adhered, it is not exposed, nor can it be exposed without destroying the product, to any temperature that would make its coating change state to become flowable and tacky. Such a transformation occurs only when the coating is exposed to temperatures above 62°C (144°F). D.I. 68, Ex. 2 (Storey Decl.) ¶7.

84. Testing by MarcTec's expert Dr. Batich confirms that the polymers in Cypher's coating cannot become flowable, tacky and adherent due to heat at the temperatures to which they are exposed in the manufacturing process. D.I. 108, Ex. 2 (Batich Rpt.) ¶¶ 72-73, 75-76, 103-105, Ex. H (stating that PEVA becomes flowable, tacky and adherent around 70°C and that PBMA becomes flowable around 90°C and tacky and adherent around 80°C); D.I. 125, Ex. 3 (Batich Tr.) 152:2-14 (agreeing that "the highest temperature during the Cordis manufacturing process that either the Cypher stent sold in the U.S. or the OUS markets are subjected to is 35 degrees Celsius" and that "the highest temperature that the Cypher stents designated for the

Japanese market are exposed to is 45, plus or minus 5 degrees Celsius."); *id*. at 148:7-149:6 (same).

85. Faced with this evidence, MarcTec argues that whether heat is "actually applied" should not be considered: "[t]he proper inquiry [according to MarcTec] thus is whether the polymers become flowable, tacky and adherent upon the application of heat, regardless of whether heat is actually applied to them during manufacture." D.I. 108 at 18. This argument distorts the claim construction adopted by the Court. "It takes heat to bond in the Bonutti invention" and the Court's construction requires that this "heat must be sufficient to cause the material to be bonded to become flowable, tacky and adherent." D.I. 175 at 28-29. The relevant inquiry is whether the polymers became flowable, tacky and adherent at temperatures which are applied to the polymers in the manufacturing process – not whether they could become flowable, tacky and adherent at temperatures which are not used. Indeed, Dr. Batich admits that exposure to temperatures of 70°C or above would damage Cypher. D.I. 125, Ex. 3 (Batich Tr.) 108:20-110:12. MarcTec fails to address this issue and has presented no evidence of infringement under the correct claim construction.

86. Instead, MarcTec relies on testimony about the effect of heat on the raw PBMA and PEVA polymers although such heat is never applied during the manufacture of the Cypher stent. Pl. Resp. at page 63. MarTec relies on testimony from Dr. Storey that the raw PBMA and PEVA polymers are capable of becoming tacky and flowable at temperatures of 77°C-150°C depending on the polymer. D.I.

108 at 18; Pl. Resp. at page 63. It, however, overlooks the operative fact – the PBMA and PEVA in the Cypher stent are never subjected to such temperatures. D.I. 108, Ex. 9 (Storey Tr.) 34-37. Dr. Storey testified as follows:

> Q. With sufficient application of heat PEVA becomes flowable, is that correct?
>
> A. My test showed that essentially that is correct. If you melt it above 80 degrees C, I could actually see flow due to capillarity through the microscope slides. *But of course in the Cypher stent it never, it is never at 80 degrees.*

Id. at 34:8-17; *see also* 34:18-35:3.

***

> Q. With sufficient application of heat PBMA can become flowable; is that right?
>
> A. Well, if you add enough heat to cause its temperature to rise to 150, it can become flowable. *Of course, that is way hotter than it's ever subjected to when it is used in the Cypher product*.

Id. at 37:15-23.

87. MarcTec also cites testimony by Dr. Maryanoff that according to the literature, "if [PEVA] is used as a melt adhesive, *it could melt at some point*." D.I. 108, Ex. 5 (Maryanoff Tr.) 74:5-16. She would therefore expect that "at that point [when it melts] it may be flowable." *Id*. This has nothing to do with the PEVA in Cypher; Cypher is not exposed to temperatures that would make PEVA melt or flow. D.I. 125, Ex. 3 (Batich Tr.) 113:13-19, 152:2-14.

88. Finally, MarcTec relies on testing and testimony from Dr. Batich that confirms noninfringement rather than infringement. Dr. Batich conducted testing

which showed that PEVA "had to be heated" to 70ºC or above in order to become flowable, tacky and adherent. D.I. 125, Ex. 3 (Batich Tr.) 107:6-12, 113:13-19; D.I. 108, Ex. 2 (Batich Rpt.) ¶¶ 72-73, 75-76, 103-105, Ex. H. Dr. Batich also showed that PBMA "had to be heated" to 80ºC or above to become tacky and adherent and 90ºC to become flowable. D.I. 125, Ex. 3 (Batich Tr.) 107:13-20; D.I. 108, Ex. 2 (Batich Rpt.) ¶¶ 72-73, 75-76, 103-105, Ex. H. MarcTec relies on this testing and testimony but ignores its import – the PBMA and PEVA in the Cypher stent are not subjected to such temperatures, D.I. 125, Ex. 3 (Batich Tr.) 152:2-14, and therefore do not become flowable, tacky and adherent. D.I. 114, Ex. 9 (Storey R.Rpt.) at 37; *see also id*. at 33.

89. In addition, as for the bonded limitation, MarcTec offers expert opinion under a facilitation standard of no relevance to this Court's claim construction. MarcTec contends that "the Cypher stent is exposed to heat that *facilitates and enhances* polymeric bonding during manufacture." D.I. 108 at 18 (emphasis added). But this is besides the point. Arguments addressing an incorrect construction have no probative value. ***PIN/NIP*, 304 F.3d at 1246**.

90. Moreover, MarcTec's facilitation arguments are based on an extreme test conducted by Dr. Batich. In arguing that PBMA will exhibit flow and become adherent during sterilization (at 35°C) and during the vacuum heat process (45°C±5°C), MarcTec relies on an experiment by its expert, Dr. Batich, which used extreme and unrealistic conditions. D.I. 108 at 18-19; Pl. Resp. at pages 15, 42, 47-48, 53-54, 59-60, 64. Dr. Batich's protocol for this test, the so-called "lap shear" test,

involved using a 2.3 kg weight to press together two strips of the polymer PBMA, which overlapped by 4 cm, on a Teflon block between a sheet of paper folded between two Dell mouse pads and then heating them to 35°C. D.I. 125, Ex. 3 (Batich Tr.) 137:9-138:15; D.I. 114, Ex. 5 at MARC10112-15. The test was "designed" by Dr. Batich. D.I. 108, Ex 2 (Batich) ¶10. As Dr. Batich admitted, there was "no established protocol for this experiment." D.I. 125, Ex. 3 (Batich Tr.) 143:1-6.

91. For his test, Dr. Batich placed a 2.3 kg weight on overlapped strips of PBMA, despite the fact that Dr. Batich was well aware that the Cypher stent is "not ever subjected to a . . . 2.3-kilogram weight" and would be destroyed if such a weight were placed on it. *Id*. at 143:7-144:1; *see also id.* at 137:9-138:15, 147:23-148:6 ("the Cypher stent is not exposed to a heavy weight to press the layers together"), 183:1-4, 294:16-18. Dr. Batich also selected an unrealistically large contact area although he was fully aware that the Cypher stent did not have a 4 cm overlap, *id*. at 145:2-10, and that an unrealistically large contact surface area increased the likelihood of adhesion. *Id.* at 144:8-23.

92. Dr. Batich acknowledged that he does not know what would happen under more realistic conditions because he did not use them in this test. *Id*. at 147:11-21. As he stated, "I didn't do tests under other conditions. So I don't know if that would happen without any weight or without some weight or lesser weight." *Id*.; *see also id*. at 184:3-6.

93. Expert opinions based on such unrealistic and "extreme experimental conditions" are inadmissible under ***Daubert***. ***In re: Silicone Gel Breast Implants***

Products Liab. Litig.*, 318 F. Supp. 2d at 902-03 (excluding another study by Dr. Batich)**. Consequently, Dr. Batich's testimony based on these extreme and unrealistic testing conditions is inadmissible as unreliable and irrelevant to the Cypher stent under ***Daubert and **FRE 702**.

94. MarcTec contends that Dr. Batich's "use of a weight during his experiment would not change his opinion that the PBMA polymer would exhibit flow and adherence at 35°C." Pl. Resp. at 53-54. But Dr. Batich only offered a "guess" that other conditions (*i.e.*, not using a weight) would show the same effect. D.I. 125, Ex. 3 (Batich Tr.) 146:10-17. He admitted that he did not observe these effects without a weight:

> Q. And without a weight, you've never detected flow, tack or adherence for either PBMA or PEVA at 35 degrees Celcius, correct?
>
> A. Correct.

Id. at 295:3-6.

He also admitted that he did not have any evidence and did not know whether PBMA would show either flow or adherence at 35°C under any other conditions. *Id*. at 146:18-21, 147:11-21 ("I didn't do tests under other conditions. So I don't know if that would happen without any weight or without some weight or lesser weight."), 184:3-6. Dr. Batich's "guess" is not good enough under **FRE 702**. ***General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997**).

95. It is telling that when Dr. Batich conducted tests without these extreme and unrealistic conditions, he "never detected" flow or adherence of PBMA at 35°C.

D.I. 125, Ex. 3 (Batich Tr.) 295:3-6. Indeed, he did not observe flow or adherence at temperatures below 80°C. D.I. 108, Ex. 2 (Batich Rpt.) ¶¶103, 105, Ex. H; D.I. 125, Ex. 3 (Batich Tr.) 107:13-20, 144:2-145:5. Testing done by Dr. Batich that did not use extreme conditions – the 2.3 kg weight and 4 cm contact area – refutes MarcTec's arguments that the polymers used in Cypher will exhibit flow or adherence during sterilization or the vacuum heat process. ***See The John Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1348-49 (Fed. Cir. 2008) (contradictory testimony by patentee's expert cannot defeat JMOL of noninfringement)**.

96. MarcTec's further assertion, based on Dr. Batich's lap shear test, that the temperature in the human body (*i.e.*, 37°C) is "sufficient to cause the PBMA polymer to flow on a micro scale and to form additional bonds," Pl. Resp. at page 14, is not supported by any evidence. If the polymers flowed in the human body or during sterilization, which they do not, the product would be destroyed. D.I. 68, Ex. 1 (Maryanoff Decl.) ¶¶37-38.

97. MarcTec contends that Dr. Batich's testing is not contradictory because one test showed that PBMA is flowable, tacky and adherent at temperatures above 80°C on "a macro scale," while the lap shear test showed that PBMA exhibited those properties at or above 35°C on "a micro scale." Pl. Resp. at pages 53-54. MarcTec's argument misses the point. Dr. Batich's testing shows that PBMA does not become flowable, tacky and adherent below 80°C on *any* scale without the use of extreme and unrealistic conditions – a weight that the Cypher stent is not subjected to and a

contact surface that is absent from the Cypher stent. The fact that PBMA may exhibit these properties on "a micro scale" under artificial conditions not present during the manufacture of the Cypher stent has no relevance to Cypher or this case. It is inadmissible under ***Daubert*** and **FRE 702**.

98. In addition, as discussed above, sterilization and vacuum heat steps – the steps that MarcTec relies on for the proposition that PBMA becomes flowable and adherent – both occur *after* the polymers are already adhered to the stent. These steps do not bond the polymers to the stent and have no bearing on this case.

99. Dr. Batich relies on solutions for flow, tack and adherence, D.I. 108 at 19, D.I. 108, Ex. 2 (Batich Rpt.) ¶111, after unequivocally stating that solutions should not be considered for flow or adherence. D.I. 108, Ex. 2 (Batich Rpt.) ¶100. Again, his contradictory positions are not sufficient to avoid summary judgment. ***Johns Hopkins*, 543 F.3d at 1348-49**. More fundamentally, as discussed above, preparation of solutions is not bonding to the device. Moreover, the temperatures used to expedite dissolution (32°C or below) are nowhere near those that testing by Dr. Batich shows are needed to cause the polymers to become flowable, tacky and adherent due to heat.

100. Finally, MarcTec claims that the "evaporation of the solvent also allows the polymer molecules to move closer to the stent's surface, increasing the adherence of the polymer coating." Pl. Resp. at page 15; D.I. 109 at 19. As discussed above, evaporation cools rather than heats. D.I. 125, Ex. 3 (Batich Tr.) 166:5-167:9. Indeed, Dr. Batich admitted that evaporation of the solvent, THF, will not heat the

polymers. D.I. 125, Ex. 3 (Batich Tr.) 167:11-14. Evaporation, therefore, cannot remedy MarcTec's failure to prove that the polymers become flowable, tacky and adherent upon the application of heat.

101. In sum, the undisputed evidence shows that no reasonable juror could find that Cypher meets the "becomes flowable, tacky, and adherent upon the application of heat" limitation of the asserted claims.

VI. MarcTec Cannot Claim Infringement Under the Doctrine of Equivalents

102. MarcTec does not dispute that Cordis is entitled to summary judgment of no infringement under the doctrine of equivalents. D.I. 108.

A. MarcTec is Precluded From Asserting the DOE for the Mechanical Device Claim Terms

103. Under the Court's claim construction, stents and devices expanded in their entirety are excluded from the scope of the claims. MarcTec therefore cannot recapture any of these structures with the DOE.

104. With stents "specifically excluded from the scope of the claims,"a stent cannot be the equivalent of something that is not a stent. ***Decisioning.com*, 527 F.3d at 1315 (citation omitted)**. MarcTec admits that "a stent cannot be the equivalent of something that is not a stent" and "does not seek to recapture" stents through the DOE. Pl. Resp. at pages 55-56.

105. Similarly, as MarcTec agrees, devices that are expanded in their entirety cannot be an equivalent of devices that are not, when the claim construction requires

that "a portion, but not all" of the device be expandable. *Id.* at page 56. MarcTec "does not seek to recapture" devices expanded in their entirety through the DOE. *Id*.

106. The "antithesis" of a construed claim element is simply not an insubstantial equivalent and "no reasonable juror could find otherwise." ***Moore*, 229 F.3d at 1106**.

107. MarcTec is also barred by argument-based estoppel from asserting the DOE to obtain coverage of stents. As this Court found, Dr. Bonutti disclaimed stents during prosecution in order to obtain allowance of his claims. D.I. 175 at 10. MarcTec is barred by Dr. Bonutti's statements from recapturing subject matter disclaimed during prosecution, *i.e.*, stents. ***Pharmacia*, 170 F.3d at 1376; *Bayer*, 212 F.3d at 1253**. Indeed, MarcTec admits that a patentee "cannot recapture subject matter that was disclaimed during prosecution." Pl. Resp. at page 59; *see also id*. at 56-57.

B. MarcTec is Precluded From Asserting the DOE for the Heat Bonding Claim Terms

108. MarcTec is barred by both argument and amendment-based estoppel from asserting the DOE against the claim limitations related to heat bonding.

109. This is so because Dr. Bonutti (1) disclaimed any methods of bonding material to devices other than by the application of heat in order for the PTO to allow his patents to issue and (2) amended all his claims to require material that is "non-flowable and non-adherent at room temperature and becomes flowable, tacky, and

adherent upon the application of heat" to make clear that his invention is limited to bonding by heat. D.I. 175 at 10-11, 28.

110. Dr. Bonutti's claims were rejected by the PTO as invalid over the prior art Palmaz '417 patent. D.I. 175 at 9; D.I. 70, Ex. L at 3. In his response to that rejection, Dr. Bonutti argued that his invention, in contrast to that of Dr. Palmaz, requires that the polymeric material be "bonded to an implant by the application of heat," not just "placed upon the wall surfaces" of the implant. D.I. 70, Ex. M at 5-6; D.I. 175 at 10-11.

111. Having disclaimed devices that have polymer bonded to the implant without the application of heat, MarcTec cannot assert the DOE for that relinquished subject matter. ***Pharmacia*, 170 F.3d at 1376; *Bayer*, 212 F.3d at 1253**. MarcTec acknowledges that a patentee cannot recapture disclaimed subject matter through the DOE and does not seek to recapture disclaimed subject matter. Pl. Resp. at page 59.

112. MarcTec is also precluded by amendment-based estoppel from asserting the DOE for the "non-flowable and non-adherent at room temperature" and "becomes flowable, tacky and adherent upon the application of heat" limitations of the claims.

113. Dr. Bonutti amended the claims of the patents-in-suit to require that the material bonded to the implant or tubular member is "non-flowable and non-adherent at room temperature, and becomes flowable, tacky, and adherent upon the application of heat." D.I. 175 at 10-11; D.I. 70, Ex. M at 2; D.I. 70, Ex. O at 2. As MarcTec admits, this amendment was made "for purposes of patentability." Pl. Resp.

at pages 57, 60. It was "made in response to the Examiner's rejection of the claims as anticipated by the Palmaz '417 patent." *Id*. at page 60.

114. Dr. Bonutti's amendment of all his claims for reasons of patentability creates a rebuttable presumption that he surrendered all equivalents for the added limitations. ***Festo*, 535 U.S. at 740**. MarcTec admits that "a rebuttable presumption that Dr. Bonutti surrendered all equivalents was created." Pl. Resp. at page 61.

115. A patentee can rebut this presumption of estoppel if he can show that one of the following three ***Festo*** criteria is applicable: (1) the alleged equivalent was not foreseeable at the time of the amendment; (2) the rationale underlying the amendment "bear[s] no more than a tangential relation" to the equivalent; or (3) there is "some other reason" suggesting that the patentee could not reasonably be expected to describe the equivalent. ***Festo*, 535 U.S. at 740-41**. *See* Pl. Resp. at page 61.

116. Although MarcTec has the burden of proof on DOE, it "has not sought to establish the applicability of any of these three ***Festo*** exceptions." Pl. Resp. at pages 61. Accordingly, MarcTec is estopped from asserting the DOE for the "nonflowable and non-adherent at room temperature" and "becomes flowable, tacky and adherent upon the application of heat" limitations of the claims.

CONCLUSION

For the reasons set forth above, the Court hereby **GRANTS** Defendants' Motion for Summary Judgment of Noninfringement (D.I. 68), finding that the Cypher stent does not infringe claims 1-6, 8, 10 and 14 of the '290 patent and claims 1, 3 and 4 of the '753 patent either literally or under the doctrine of equivalents. Summary judgment shall be entered in favor of defendants Johnson & Johnson and Cordis Corporation and against plaintiff MarcTec, LLC. Lastly, the Court hereby **FINDS AS MOOT** all other pending Motions remaining in this case (D.I.'s 114, 120. 127, 129, & 130).

IT IS SO ORDERED.

Signed this 15th day of June, 2009.

/s/ David R Herndon

Chief Judge
United States District Court